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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,158

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Emmanuel Delorme

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COLOPLAST CORP.

I.P. DEPARTMENT, U.S. OPERATIONS

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/811,158	<b>Applicant(s)</b> DELORME ET AL.	
	<b>Examiner</b> KRISTEN C. MATTER	<b>Art Unit</b> 3771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22,36-39,41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,36-39,41 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/12/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

This Action is in response to the amendment filed 5/2/2008. Claims 22, 36-38, 41, and 42 have been amended and no claims have been added or cancelled. Currently, claims 22, 36-39, 41, and 42 are pending in the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "the upper and lower stabilizers" in line 10. There is insufficient antecedent basis for this limitation in the claim because the lower stabilizers have not been previously claimed.

Claim 39 is dependent on claim 38 and is therefore rejected for the same reasons outlined above with respect to claim 38.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 22, 36-39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacquetin US 7,131,944 B2 in view of Gellman WO 98/35632.**

**As to claim 22**, Jacquetin discloses an implant in figures 1-11. In column 2 lines 50-54 Jacquetin discloses material for the implant being bio-compatible mesh material such as a knitted polypropylene fabric (e.g., soft PROLENE...). This soft nature of the fabric allows the implant to be adapted to be placed in the vaginal fornix to treat rectocele and/or prolapsus. Jacquetin in column 2 lines 6 and 7 further discloses the implant is for treating rectocele and/or a hysterocele present in a female patient. Jacquetin in column 2 lines 50 and 51 discloses the implant is made from a single sheet of mesh material, which makes the implant thin, and in column 3 lines 9 and 10 Jacquetin discloses the implant can be sized and shaped to meet the need of a particular patient. Being able to size and shape the implant make the implant flexible. Figure 10 shows a support body (112/114) from which there extend suspension stabilizers (142 and 144). Figure 10 further shows at least two upper suspension stabilizers which are disposed on either side of a

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sagittal plane and have longitudinal axes forming between them an angle greater than 45 degrees, and two lower suspension stabilizers disposed on either side of the sagittal plane.

Jacquetin however lacks wherein the implant body presents, in its upper region, at least two orifices for passing posterior stabilizers of an anterior prosthesis once the stabilizers have passed through the uterosacral ligaments. However, Gellman in a urethral suspension slings/implant teaches a body (12) with upper region having two orifices (18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jacquetin in order to provide the body with two orifices at the upper region for the purposes of providing suture receiving sites as taught by Gellman (see page 7 line 19).

**As to claim 36**, Jacquetin discloses the implant as applied for claim 22. Jacquetin however does not explicitly teach the location of the upper and lower stabilizers as claimed. However, Jacquetin in column 3 lines 9 and 10 discloses the implant can be modified by the surgeon to accommodate different patients. Furthermore, it would have been obvious to one of ordinary skill in the art to place the stabilizers at the treatment site, and for rectocele or prolapsus of the vaginal fornix it would have been obvious to one of ordinary skill in the art to place the implant such to cover gluteal, pubo-rectal, and uterosacral region since these areas are likely to be herniated/protruded in patients who are diagnosed with rectocele. Therefore, the step of placing the upper suspension stabilizers through the gluteal region, the lower suspension stabilizers through the pubo-rectal region and the support body in the uterosacral region would have been obvious to one of ordinary skill in the art when treating a patient with rectocele.

**As to claim 37**, Jacquetin discloses the implant as applied for claim 22. Jacquetin however does not explicitly teach the location of the upper and lower stabilizers as claimed.

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However, as applied for claims 22 and 36, Jacquetin's implant can be modified by the surgeon to accommodate different patients. Furthermore, it would have been obvious to one of ordinary skill in the art to place the stabilizers at the treatment site, and for rectocele or prolapsus of the vaginal fornix it would have been obvious to one of ordinary skill in the art to place the implant such to cover sacrosciatic, pubo-rectal, and uterosacral regions since these areas are likely to be herniated/protruded in patients who are diagnosed with rectocele. Therefore, the step placing the upper suspension stabilizers through the sacrosciatic region, the lower suspension stabilizers through the pubo-rectal region, and the support body in the uterosacral region would have been obvious to one of ordinary skill in the art when treating a patient with rectocele.

**As to claim 38**, Jacquetin discloses the implant as applied for claim 22. Jacquetin lacks the middle suspension stabilizers. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the middle stabilizer, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ8. Furthermore, because Jacquetin discloses that the extra arms are simply for increasing lateral support (column 9, lines 30-35) it appears as though the device would perform equally well with additional middle stabilizers.

Jacquetin further does not explicitly teach the location of the upper and lower stabilizers as claimed. However, as applied for claims 36 and 37, Jacquetin's implant can be modified by the surgeon to accommodate different patients. Furthermore, it would have been obvious to one of ordinary skill in the art to place the stabilizers at the treatment site, and for rectocele or prolapsus of the vaginal fornix it would have been obvious to one of ordinary skill in the art to place the implant such to cover sacrosciatic, pubo-rectal, perineal regions, and rectovaginal

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septum since these areas are likely to be herniated/protruded in patients who are diagnosed with rectocele. Therefore, the step placing the upper suspension stabilizers through the sacrosclatic region, the middle stabilizers through the pubo-rectal region, the lower suspension stabilizers through the perineal region, and the support body in the rectovaginal septum would have been obvious to one of ordinary skill in the art when treating a patient with rectocele.

**As to claim 39**, Gellman teaches posterior stabilizers of an anterior prosthesis as sutures that is received by orifices (18) on the body (see col.7 line 19). These sutures passing through the orifices (18) at the upper portion of the implant allow support the upper portion of the implant. Sutures of Gellman are acting as the posterior stabilizers of an anterior prosthesis.

**As to claim 41**, Jacquetin/Gellman teaches the claimed invention as applied for claim 22. Jacquetin in column 2 lines 51-54 further teaches claimed biocompatible material.

**As to claim 42**, Jacquetin/Gellman teaches the claimed invention as applied for claim 22. Jacquetin in figure 10 shows the implant is substantially flat and hammock-like.

### ***Response to Arguments***

Applicant's arguments filed 5/2/2008 have been fully considered but they are not persuasive.

In response to Applicant's arguments that only the "anterior implant" of Jacquetin has the four arms and is therefore not for treating rectocele. Examiner first notes that the apparatus claims 22, 41, and 42, are for "treating rectocele and/or prolapsus." Cystocele (which applicant claims is treated by the anterior implant of Jacquetin) is in fact a prolapsus and therefore either of the anterior or posterior implants of Jacquetin could read on the instant claims. In addition,

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examiner points to column 4, lines 5-15 in which Jacquetin discloses that the anterior and posterior implants can be formed separately or monolithically (therefore they can be considered for treating both anterior and posterior ailments). Furthermore, given that the extra arms are merely for additional lateral support, there appears to be no reason why one of ordinary skill in the art would not find it obvious to provide both the posterior and anterior supports with more than 2-4 arms in order to provide a desired amount of support for treatment as a mere duplication of parts. Therefore, it appears to the examiner that any combination of arm numbers using one or both of the anterior and posterior implants of Jacquetin can be selectively used by a physician to treat a particular patient's condition as needed.

In response to applicant's arguments that Gellman would not be used to treat prolapse conditions, examiner asserts that Gellman is cited merely as showing that it is well known to use orifices for selectively attaching various implants and sutures together. Since multiple implants are commonly used for treating prolapsus (as evidenced by the instant applicant and teachings of Jacquetin), examiner holds that one of ordinary skill in the art would find it obvious to add orifices to the implants as taught by Gellman for allowing multiple implants to be secured together since this technique is well known and commonly used in implantation surgery.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**



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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771

/Kristen C. Matter/  
Examiner, Art Unit 3771